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| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|---|-------------------------|------------------------|------------------|
| 10/031,149 | 06/03/2002 | | Stephen Douglas Barrett | A0000104-01-SMH | 8665 |
| 7590 05/11/2005 | | | | EXAMINER | |
| Suzanne M Harvey Warner-Lambert Company 2800 Plymouth Road | | | | WANG, SHENGJUN | |
| | | | | ART UNIT | PAPER NUMBER |
| Ann Arbor, M | | 5 | | 1617 | |
| | | | | DATE MAILED: 05/11/200 | 5 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary Examiner Shengjun Wang The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed | | | | | |
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| after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1) Responsive to communication(s) filed on 16 February 2005. | | | | | |
| 2a)⊠ This action is FINAL . 2b)□ This action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4)⊠ Claim(s) <u>1-20 and 25-32</u> is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>1-20 and 25-32</u> is/are rejected. | | | | | |
| Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| The attached detailed Office action for a list of the certified copies flot received. | | | | | |
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| Attachment(s) | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | |

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DETAILE D ACTION

Receipt of applicants' amendments and remarks submitted February 16, 2005 is acknowledged.

Initially, it is noted claims 14 read on the elected invention and should have been included in the rejections.

Double Patenting Rejections

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20, 25-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-42 of U.S. Patent No. 6,545,030.

Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 22-42 in '030 directed to method of using the compound herein for treating patient with stroke, cancers, osteoarthritis, arthritis, infections, Septic shock, complication of diabetes, transplant operation, etc. Note it should be well understood that many of the cancer patients, stroke patients, or patient with complication of diabetes suffer neuropathic pain.

Therefore, practicing the claims in '030 would effectively practice the claimed invention herein.

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Claim Rejections 35 U.S.C. 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-20, 25-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Barrett et al. (US 6,545,030).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

5. Barrett et al. teach the compounds herein and the method of using the same method of using the compound herein for treating patient with stroke, cancers, osteoarthritis, arthritis, viral infections, Septic shock, complication of diabetes, transplant operation, etc. Note it should be well understood that many of the patients, particularly the cancer patients, stroke patients, or patients with complication of diabetes, suffer pain, neuropathic pain in particular. Therefore, practicing the claims in '030 would effectively practice the claimed invention herein. See, particularly, col. 2-4, and the claims, particularly, claims 18-42.

Response to the Arguments

Applicants' amendments and remarks submitted February 16, 2005 have been fully considered. The amendments and remarks are persuasive with regard to the rejections over Boschelli et al., but are not persuasive with respect to the rejections of US patent 6,545,030.

Regarding the rejections over '030, applicants argue that treating pain as herein claimed is not an obvious variation of treating arthritis, cancer, stroke, etc, as claimed in '030. The examiner agrees that treating pain as herein claimed is not an obvious variation of treating arthritis, cancer, stroke, etc, as claimed in '030. However, this is not the issue raised in the rejections. As stated above, it should be well understood that many of the cancer patients, stroke patients, arthritis patients, or patient with complication of diabetes suffer neuropathic pain. Therefore, practicing the claims in '030 would effectively practice the claimed invention herein. Note the fact that applicant has recognized another advantage (i.e., reducing pain) which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Applicants' attention is further directed to Ex parte Novitski, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a haec verba recitation for such utility. In the instant application, as in Ex parte Novitski, supra, the claims are directed to treating or preventing a malady or disease with old and well-known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a therapeutic utility anticipates claims directed to such therapeutic use. Arguments that such therapeutic use is not set forth haec verba are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification

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limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated therapeutic utility, renders such claims anticipated by the prior inherent use.

In response to the final rejection, applicants are advised to amend claims 27-32 by canceling any compound that not read on elected invention.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUNWANG PRIMARY EXAMINATE Shengjun Wang Primary Examiner Art Unit 1617